204. According to CW2, inclusion in the ADAP formulary means that all AIDS/HIV patients covered by the program receive the drug and sales increase exponentially. Prior to Viread's inclusion in the Georgia ADAP formulary, CW2 sold approximately between \$10 million and \$15 million of Viread. Of those sales, CW2 estimates that 85%-90% were a result of off-label marketing. After inclusion of the Georgia ADAP formulary (late 2002 through early 2004), CW2 sold approximately between \$15 million and \$20 million of Viread. Again, CW2 states that 85%-90% of those sales were caused by off-label marketing. Like other Confidential Witnesses, CW2's off-label marketing involved: (1) marketing to HIV patients co-infected with Hepatitis B; (2) marketing Viread as a first-line or initial therapy; and (3) marketing against Viread's safety profile.

205. Based on his/her own off-label Viread sales, CW1 believes that 75%-95% of all sales of Viread in the United States were the result of off-label marketing. Indeed, one has only to compare Gilead's explosive growth from 2002 to 2003 to see the effect that off-label marketing had. Viread sales in the first quarter of 2002 were \$27.1 million, compared with \$107 million in the first quarter of 2003. Viread sales in the second quarter of 2003 were a whopping \$167 million – up from \$44.7 million in the second quarter of 2002. Indeed, CW3 recalled that treatment naïve sales grew dramatically as the Company made a push to increase sales through off-label marketing at the end of 2002 and beginning of 2003.

206. CW6's experience selling Viread off-label in the New York City market led her/him to estimate that at least 70% of her/his sales were off-label for use by treatment naïve patients. Adding in the fact that she/he was also encouraged to market Viread off-label to Hepatitis patients, and CW6's experiences corroborate CW1 and CW2's estimates of the extent of Gilead's off-label sales. Specifically, CW6 stated her/his total sales of Viread for the 2003 timeframe were approximately \$400,000 to \$500,000 per month. Thus, during 2003, CW6 sold approximately between \$4,800,000 and \$6,000,000 of Viread, of which at least between \$3,360,000 and \$4,200,000 (i.e., 70%) resulted from off-label marketing and sales. Taking out the dramatic impact of off-label marketing to treatment naïve patients, CW6 would have only sold between \$120,000 and \$150,000 of Viread per month during 2003, for a total of between \$1,440,000 and \$1,800,000 for all of 2003.

207. Moreover, Gilead's domestic Viread sales were \$115.6 million in the second quarter of 2003, compared with \$29.2 million in the second quarter of 2002. Based on CW1's information, which is bolstered by the accounts of all the Confidential Witnesses, off-label sales accounted for between \$86.7 million and \$109.82 million in the second quarter of 2003. The staggering impact of off-label marketing is underscored by the seriousness of the off-label marketing as described in the Untitled Letter and the FDA Warning Letter.

was pervasive. According to CW1, sales representatives would discuss amongst themselves which off-label materials and marketing tactics were generating the most sales. CW1 knows this because of CW1's experiences on the Gilead Field Marketing Advisory Committee, which exposed CW1 to Therapeutic Specialists and Gilead executives from all regions of the United States. In addition, CW1 would discuss sales techniques with successful Therapeutic Specialists in other regions of the country in an effort to find out what methods worked best for them. These discussions included descriptions of off-label marketing techniques. In addition, according to a former Therapeutic Specialist who was part of Viread's launch and with the Company through June 2002, the sales force was supplied with documents listing physicians and a profile of the drugs they prescribed. The list would allow sales representatives to tailor their Viread pitch to suit the prescribing patterns of the various doctors and explain why Viread was superior to the drugs the physician had been prescribing.

209. As a result of Defendants' off-market labeling, physicians prescribed Viread for purposes not specifically approved by the FDA. For example, according to an AIDS-specialist physician who treats between 2,000 and 2,500 AIDS patients in the Western United States, he routinely uses Viread off-label to treat Hepatitis B co-infected HIV patients. In addition, this physician began using Viread as a first line antiretroviral therapy in early 2003, before it was approved by the FDA in late 2003 for this purpose, in response to unsolicited data this physician received from Gilead concerning Study 903 and the use of Viread in treatment naïve patients.

210. As described above, during the Class Period Viread was never indicated for treatment in patients who are co-infected with HIV and Hepatitis B – the FDA had not approved such a use of

Viread and thus prohibited any marketing of Viread for treatment of co-infected patients. In fact, the FDA warned against this practice, as described above, in a black box warning – the strongest warning possible – in the Viread label.⁴

211. Additional data supports the accounts of the Confidential Witnesses. According to the "HIV Therapy Audit," a quarterly physician survey designed to monitor HIV+/AIDS patients who are seeking treatment and their associated drug and non-drug therapy that was conducted by Verispan, LLC, HIV patients co-infected with Hepatitis B first began using Viread in the third quarter of 2002. At that time, 55.5% of co-infected patients surveyed used Viread. By the third quarter of 2003, 72.7% of co-infected patients surveyed were using Viread, despite the fact that: (1) no data existed that conclusively demonstrates that Viread effectively treats Hepatitis B infection, with or without HIV co-infection; (2) the FDA had never approved of the use of Viread in HIV and Hepatitis B co-infected patients and, indeed, specifically warned against it; and (3) HIV resistance to antiretrovirals, such as Viread, leads HIV positive patients to change their drug regimens, exposing co-infected patients using Viread to severe acute exacerbations of Hepatitis B infection.

212. The 72.7% from the third quarter of 2003 figure translates into roughly 26,000 patients, based on the fact that roughly 10% of the HIV infected population are co-infected with Hepatitis B, and approximately 360,000 HIV patients receive antiretroviral treatment such as Viread. See United States Centers for Disease Control's ("CDC") Morbidity and Mortality Weekly Report ("MMWR") (available through the CDC's website (http://www.cdc.gov/mmwr); see also

⁴ The FDA warning label for Viread also advised healthcare professionals to check HIV patients for Hepatitis B co-infection, prior to the patients taking any Viread, to prevent instances of liver failure in the event an HIV patient has to change his or her drug regimen and stop taking Viread due to HIV resistance.

⁵ Verispan describes itself as "revolutionary health care information company" that "is the leading provider of patient-centric, longitudinal data delivered in near real time as well as one of the major providers of health care information overall." "Verispan has secured rights to data from more than half of all U.S. prescriptions and over 20% of all U.S. electronic medical transactions annually. Verispan captures at least 25% of all prescriptions from 98% of all three-digit zip codes and at least 45% of all prescriptions from almost 80% of all zip codes. This pervasive data coverage means that Verispan can provide better insight into prescription and medical activity at the national, regional and individual prescriber level than ever before possible." *See* http://www.verispan.com/about/.

http://www.gilead.com/wt/ltd_slideshow/hiv.⁶ This data is bolstered by the account of CW7, who stated that 10% of her/his total Viread sales were to Hepatitis B infected patients.

- 213. Defendants also increased Viread sales by improperly marketing Viread as a first-line (initial) therapy for treatment naïve HIV patients, before Viread was indicated for these patients. Until late 2003, Viread was not indicated for use in treatment naïve patients. Not content to await FDA approval of Viread as a first-line antiretroviral drug, Defendants immediately used off-label marketing to sell Viread as a first-line HIV therapy upon launching Viread in October 2001.
- 214. According to an Infectious Disease Specialist in the Southeast United States with a large AIDS practice that comprises 40% to 45% of his total practice, he began to receive unsolicited advice on using Viread as a first line HIV therapy from Gilead sales representatives shortly after Viread was launched in October 2001. He then began to use Viread as a first line therapy in 2002. A second Infectious Disease Specialist in the Southeast United States also received unsolicited material from Gilead representatives on the use of Viread as first line therapy upon Viread's October 2001 launch. The second Infectious Disease Specialist began using Viread as a first line therapy in 2001.
- 215. According to the HIV Therapy Audit, in the fourth quarter of 2001 (shortly after its launch), approximately 11.2% of patients taking Viread in the U.S. were using it as a first-line treatment. By the third quarter of 2003, Defendants' improper off-label marketing had increased that number had to 23.8%. Thus, out of roughly 83,000 patients on Viread by the third quarter of 2003 (according to the HIV Therapy Audit), almost 20,000 were using Viread as a first-line therapy.
- 216. Gilead also marketed Viread against its safety label. Gilead sales representatives routinely represented that Viread had no side effects and was as safe as placebo. Martin called it a "miracle product." According to the Medical Director of a large AIDS clinic in Washington, D.C. who uses Viread routinely in patients, Gilead representatives told him that Viread was completely safe as safe as placebo. In particular, the Medical Director said that the Gilead representatives

⁶ Likewise, an informal survey of AIDS physicians resulted in reported co-infection rates of between 5% and 30%.

marketed Viread as completely safe with regard to renal function. The Medical Director stated that based on these false representations (off-label marketing), he wrote prescriptions for Viread. Since prescribing Viread based on false safety marketing, the Medical Director has had patients develop renal (kidney) failure due to Viread and is now cautious about using Viread. This Medical Director stated that he felt he had been deceived about Viread's safety profile by Gilead drug sales representatives.

- 217. Similarly, an AIDS specialist from the Western United States was told by Gilead representatives that Viread was a safe drug without nephrotoxicity (risk of renal problems). This AIDS specialist has since found that nephrotoxicity is a problem with Viread contrary to what Gilead sales representatives told her. Likewise, a Doctor of Pharmacy practicing in the Mid-West United States, who has 20% of the patients in her AIDS clinic on Viread, was told by Gilead sales representatives that Viread had a safety profile similar to placebo. Since then, she has seen increasing frequency of renal insufficiency in patients on Viread in direct contravention to Gilead's off-label marketing tactics.
- 218. The Verispan data, the data collected from public sources, and the estimates of confidential sources, including many physicians, demonstrate that extraordinary amounts of Viread were prescribed as a direct result of Defendants' off-label marketing. Extrapolating from Verispan's survey data, nearly 20,000 patients were taking Viread as a first-line therapy, 26,000 co-infected patients were taking Viread, and certainly large numbers of Viread patients were obtained by marketing against the safety label. This data, which includes the Verispan data, is therefore in line with and corroborates all of the Confidential Witnesses' estimates that off-label marketing formed the basis for the Company's sales culture, including CW1 and CW2's estimates that 75% to 95% of Viread sales during the Class Period were caused by off-label marketing, and CW6's estimate that at least 70% of her/his Viread sales were caused by off-label marketing to treatment naïve patients.
- 219. The Verispan data is based on surveys of physicians. As a result, it is not a complete picture of Viread's use as a result of off-label marketing. Gilead's financial statements in their SEC filings, however, corroborate the Verispan data. Gilead's financial data shows Viread sales growing from its launch through the Class Period from revenue of \$13 million to revenue of \$115 million. At

the same time, Viread sales became a larger percentage of Gilead's total sales from 22.1% at the fourth quarter of 2001 to 59.5% at the third quarter of 2003.

- 220. Whether using the data extrapolated from Verispan, whether using the 75% to 95% estimate of Viread sales resulting from off-label marketing as calculated by CW1 and CW2, the 70%-plus estimate calculated by CW2, or whether taking into account the collective experiences of all of the Confidential Witnesses, the results are not only material, but stunning.
- 221. Defendants will likely (because they have in the past) argue that the fact that 75% 95% of CW1's and CW2's sales of Viread, as well as at least 70% of CW6's sales of Viread, were a direct result of off-label marketing (amounts that Gilead cannot dispute are material) does not mean that 75% 95% of Gilead's Viread sales were caused by off-label marketing. However, taking all of the allegations of this Complaint as true, it is clear that the Court should draw an inference that Gilead's company-wide Viread sales were materially artificially inflated as a direct result of off-label marketing.
- 222. The inference that Gilead's Viread sales were materially artificially inflated by off-label marketing is supported by, among other things: (1) the intensity and frequency with which Gilead ordered its sales force to use off-label marketing; (2) the pressure put on all of the Confidential Witnesses to disseminate and actually utilize off-label marketing; (3) the volume of CW1, CW2, and CW6's Viread sales caused by off-label marketing; (4) the fact that off-label marketing materials were deliberately delivered to the sales force through the Company's training department; (5) the FDA letters, which corroborate the Confidential Witness allegations that there was a deliberate, covert effort to engage in systemic off-label marketing; (6) the statistical evidence of the levels of off-label sales; and (7) the familiarity that CW1 (especially as part of the Field Advisory Board) and CW2 have with other Gilead sales people and their knowledge that other Gilead sales people use off-label marketing to sell Viread.
- 223. Indeed, every indication is that the use and impact of the off-label marketing was across-the-board. Even if the Court were to, for the sake of argument, cut CW1's and CW2's estimates in half, to 35% 45%, the impact of off-label marketing is material.

E. The Effect of Defendants' Fraudulent Promotion of Viread on Drug Wholesalers and Wholesaler Inventory Over-Stocking

- 224. At all relevant times, the major national wholesalers of Viread were McKesson Corp., Cardinal Health, Inc., and AmeriSource-Bergen Corp.
- 225. According to a former Vice President/Division Manager of national wholesaler AmeriSource-Bergen, the major national wholesalers purchase approximately ninety-percent (90%) of the drugs sold by drug manufacturers.
- 226. It is common knowledge among industry insiders, including Defendants, that wholesalers make very little, if any, profit when re-selling manufacturers' drugs purchased at their usual price. In fact, according to a former Marketing Manager for national wholesaler Bergen Brunswig, wholesalers generally only realize a profit when they sell products to retailers at minimal margins, or when they stockpile mass quantities of the product prior to a price increase and then sell it at the new price. Wholesalers do this by overstocking a product at the lower price.
- 227. Several former Gilead employees including CW1 and CW2, a Director of National Sales, and a Regional Sales Director, confirmed that like others in the industry, Gilead executives and employees were well aware of this business strategy. In fact, according to a former Gilead Regional Sales Director, while at the San Francisco National Meeting, Defendant Perry acknowledged to several employees that wholesalers were overstocking in anticipation of a Gilead price increase. Indeed, this "buy at the old price, sell at the new price" business plan is so widely relied upon that the national wholesalers have employees whose only job is to meet with manufacturers, find out when price increases are going to take place, and assist their purchasing departments with overstocking the drugs.
- 228. Likewise, drug manufacturers employ trade relations people whose job is to interact with drug wholesalers and provide them with information about upcoming price increases and other product information. According to CW1, Gilead employed at least two people in this capacity.
- 229. As described by these industry insiders, drug manufacturers such as Gilead not only know about the "buy at the old price, sell at the new price" wholesaler strategy, but encourage and perpetuate it. They do this by informing wholesalers in advance that a price increase is going to take

place. Gilead did just that, artificially boosting sales of Viread, in conjunction with its false, misleading and illegal promotion of Viread, and announced to wholesalers that a price increase for Viread would take effect in June 2003. Consequently, motivated by the temptation of increased margins and emboldened by Gilead's illegally inflated sales and artificially inflated demand for Viread, the major drug wholesalers stockpiled mass quantities of Viread in advance of the June 2003 price increase. This wholesaler stockpiling would not have occurred but for the off-label marketing and the resulting creation of an artificially increased demand for Viread. Thus, the wholesaler overstocking was also caused by Gilead's illegal off-label marketing scheme.

- 230. By increasing the price of Viread in June 2003, Defendants furthered their fraudulent scheme. Conveniently, the resulting wholesaler overstock confirmed the impression that Viread was in high demand and that Gilead's financial and operational results were strong.
- 231. Defendants routinely used wholesaler sales to improve overall Viread sales. For example, on April 2, 2003, Meyers sent an e-mail to sales representatives, including Rich, DelloStritto, and Kaiser, among others, discussing the need to meet sales figures for Viread. The e-mail was copied to, among others, defendants Martin, Perry, Milligan, and Bischofberger. Attached to the e-mail was a chart entitled "Kicker Bonus Forecast." The Kicker Bonus Forecast set forth Viread's Financial Forecast of sales from October 2002 through April 2003 and the corresponding actual sales. The chart indicated that to meet the seven month sales forecast, April's actual Viread sales needed to be \$38.3 million, \$7 million more than the April forecast of \$31.9 million. According to CW1, Gilead made the sales numbers by overloading wholesalers with product. Wholesalers were willing to overstock because they were tricked into believing that the off-label marketing-created "demand" for Viread was real.

DEFENDANTS' CLASS PERIOD MATERIALLY FALSE AND MISLEADING STATEMENTS

232. The Class Period begins on July 14, 2003. On that date, Gilead issued a press release entitled "Gilead Sciences Expects Second Quarter 2003 Financial Results Will Exceed Expectations" and reported that, because of dramatically increased demand for Viread, its financial results for the

previous quarter (Second Quarter 2003) would "exceed expectations." In pertinent part the Company stated:

Gilead Sciences, Inc. today announced that based on initial analyses, the company expects that its financial results for the second quarter 2003 will exceed analyst expectations, driven primarily by higher product revenues.

Gilead estimates its total net revenues for the second quarter 2003 will be in the range of \$236-239 million. Median total net revenues projected by analysts who report their earnings forecasts to FirstCall are \$179 million. The increase in revenue was driven primarily by strong sales growth of Viread® (tenofovir disoproxil fumarate), one of the company's antiviral drugs for the treatment of HIV. Gilead expects that Viread sales will be approximately \$165 million for the quarter, compared to \$107 million for the first quarter of 2003. Increasing Viread sales reflect broader prescribing patterns in all commercial markets, as well as increases in U.S. wholesaler inventory levels in the second quarter in anticipation of a Viread price increase, which was implemented on June 27, 2003.

(Emphasis added.)

- 233. Defendants' statements in this press release regarding Gilead's sales of Viread, including sales results and the reasons for increased Viread sales, were materially false and misleading because, as detailed in the Section entitled "Factual Detail Undermining the Truth of Defendants' Class Period Representations," Defendants' marketing and promotional activities for Viread were not in compliance with FDA approved guidelines, violated federal laws, and created serious public health and safety implications for Viread users. Defendants' false, misleading, and illegal marketing and promotional activities prior to and during the Class Period had the cause and effect of materially increasing the volume of prescriptions for Viread at all relevant times. Their activities also had the cause and effect of materially boosting the Viread inventory of U.S. drug wholesalers. Defendants' fraudulent Viread promotional scheme was designed to, and did, create the false and misleading public impression that demand for Viread was strong and that Viread sales would continue to increase.
- 234. Analysts and the market took Defendants' July 14, 2003 press release as welcome news. Analyst Eric Schmidt of SG Cowen Securities expressed amazement at Gilead's ability to beat expectations by such a wide margin. A July 14, 2003 *Bloomberg News* report quoted Schmidt as follows:

12

13

11

14 15

16 17

19

18

20 21

22 23

> 24 25

26

27 28

"The earnings could be as high as double the Street consensus, which would really be remarkable," said Schmidt, who rates Gilead shares "market perform" and doesn't own them. "I can't remember a biotech company of this size beating expectations by two-fold before."

Analysts cautioned that Viread sales may have been driven materially by wholesalers 235. stocking up ahead of a June 2003 price increase, signaling weak demand for Viread. In this regard Bloomberg News reported:

It's not clear how much of the increase in Viread sales came as wholesalers stocked up on the drug ahead of a price increase that took effect last month, said Michael King, an analyst at Banc of America Securities. "I'm going to be a little bit careful about whether the second-quarter Viread numbers represent a new level because of the inventory," said King, who rates the stock "buy" and owns none.

- As a result, Defendants acted quickly to neutralize analyst concerns, assuring 236. investors that increased prescriptions (indicating increased demand) were driving Viread sales, in addition to any inventory overstocking.
- Specifically, on July 14, 2003, Gilead's spokeswoman, Amy Flood, stated in 237. Bloomberg News: "It he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking."
- In response to the July 14, 2003 news, the price of Gilead shares soared by \$7.97 per 238. share in one day, closing at \$67.25 on July 14, 2003 (up from the previous day's close of \$59.28 per share) – a single day increase of 13.4% and a near-record high.
- Notwithstanding, Amy Flood's July 14, 2003 statement was false and misleading 239. because it was designed to, and did, create the false impression that demand for Viread was strong. In reality, as detailed herein, Defendants' false, misleading and illegal marketing and promotion of Viread was artificially boosting sales of and demand for Viread, which in turn persuaded wholesalers to overstock Viread in response to the announced price increases.
- Just days after Gilead's announcement of its second quarter 2003 results, on July 29, 240. 2003, the DDMAC issued the FDA Warning Letter. The letter was addressed to Defendant Martin and required Gilead to cease and desist from its repetitive, illegal promotion of Viread. The FDA was particularly concerned about Gilead's illegal practices because of significant public health and safety concerns, Gilead's blatant disregard of the FDA's prior written warnings, and because of

illegal promotional practices at the well-attended Miami conference on March 31-April 2, 2003. See
¶¶178-86, supra. After that conference, attended by more than 1,500 guests seeking information
regarding the efficacy of Viread, Gilead reported outstanding sales increases for Viread during
Second Quarter 2003 (which included April, May and June 2003, the months following the Miami
conference).

241. Indeed, on July 31, 2003, the Company issued a press release reporting its Second Quarter 2003 results and announcing that revenues for the quarter were reportedly \$238.9 million, in line with its July 14, 2003 preannouncement:

Net revenues from product sales totaled \$230.7 million, up 146 percent from the second quarter of 2002. This growth primarily was driven by higher revenues from Viread® (tenofovir disoproxil fumarate). Sales of Viread were \$167.0 million in the second quarter of 2003, up from \$44.7 million in the second quarter of 2002 and \$107.3 million in the first quarter of 2003. Viread sales growth was primarily driven by higher prescription volume, a significant increase in U.S. wholesaler inventories and a favorable European currency environment compared to the same quarter last year. Gilead estimates that increased stocking by U.S. wholesalers accounted for \$25-30 million of Viread sales in the second quarter. AmBisome® (amphotericin B) liposome for injection sales for the second quarter of 2003 were \$51.2 million, an increase of 7 percent compared to the second quarter of 2002. Reported AmBisome sales in the second quarter of 2003 were \$7.0 million higher due to the favorable currency environment compared to the same quarter last year. On a volume basis, AmBisome sales decreased by 4 percent in Europe compared to the second quarter 2002. Sales of Hepsera® (adefovir dipivoxil 10 mg) totaled \$12.4 million for the second quarter of 2003, up from \$5.8 million in the first quarter of 2003.

"We are very pleased to report another quarter of significant increases in product revenues. This strong growth was fueled primarily by increasing sales of Viread in all marketed territories and Hepsera's uptake in the United States and introduction in Europe," said John C. Martin, PhD, President and Chief Executive Officer of Gilead Sciences. "We are focused on *continuing this sales momentum and increasing our market share through robust clinical data and label expansions* in key territories, as well as launching EmtrivaTM (emtricitabine) for HIV."

(Emphasis added.)

242. This July 31, 2003 press release is false and misleading for the reasons set forth in ¶233 and the factual detail contained throughout this Complaint regarding Defendants' false, misleading, and illegal promotion of Viread. In addition, the July 31, 2003 press release announcing "higher prescription volume," "continuing[] sales momentum" and increased market share through "robust clinical data and label expansions" was particularly egregious, given that two days before its

28

27

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

25

26

release the FDA had issued repeated warnings and cease and desist instructions to Gilead (addressed to Defendant Martin) for its illegal Viread promotional campaign.

- 243. Market analysts took note of the announced wholesaler overstocking and took it into account in their assessment of Viread's performance. Even with the overstocking, however, analysts were impressed with Gilead's second quarter results.
- 244. For instance, on July 31, 2003 Morgan Stanley issued a research note titled, "Gilead Sciences: Still Something Left on the Table." The note attributed Gilead's second quarter results to "broader prescribing patterns and market share gains in all markets, currency benefit in Europe . . . as well as the increase in US wholesaler inventories." The increased inventories did not concern Morgan Stanley, however, because it believed that, in light of Viread's strong growth, wholesaler inventories had been historically low. In Morgan Stanley's estimation, Viread's performance justified higher inventory levels, and thus, it did not expect that the overstocking would damage Viread's third quarter performance too badly: "We estimate that US wholesaler inventories were about 3.5 weeks entering 2Q, versus an average of about 4.5 weeks for Viread historically and a pharmaceutical industry average of about 5.8 weeks. Thus, we believe that there will be a limited impact of inventory draw-down in 3Q"
- 245. On August 1, 2003, Prudential Financial issued a report attributing the stellar second quarter results to "stronger than expected prescription data, an increase in U.S. inventory levels, and favorable foreign exchange rates." Prudential estimated that industry stocking, plus the foreign exchange benefit, to total \$35 million. Even taking the overstock into account, the strong demand for Viread persuaded Prudential that full year sales of the drug would total \$625 million.
- 246. Even as late as October 8, 2003, Bear Stearns projected third quarter Viread sales of \$136 million a figure that, it said, took into account an estimated \$30 million of wholesaler inventory build-up in the second quarter of 2003.
- 247. Unbeknownst to the market, however, the favorable results that Gilead had reported had been based on artificially inflated demand as a result of illegal off-label marketing. Artificially inflated demand not only fueled prescriptions and sales, but had also induced wholesalers to stock up

on Viread. These wholesalers had purchased the extra Viread in anticipation of continued strong growth in demand for the drug.

- 248. As analysts were touting Viread's strong second quarter performance, just three business days after the FDA Warning Letter issued but before it was disclosed to the market -- on August 5, 2003 Defendants began dumping their Gilead common stock at a furious pace. In total, the Individual Defendants sold 324,601 shares of Gilead at artificially inflated prices in a single month, reaping gross proceeds of \$20,682,070.78. The average selling price was \$64.10 per share, near the stock's peak at \$70.61 per share.
- 249. On August 7, 2003, the FDA Warning Letter became public. Investors, aware of the letter but unaware of the extent to which Gilead's entire business model depended on off-label marketing, did not attribute much significance to it.
- 250. For instance, postings on the Yahoo! Message Board devoted to Gilead on August 7, 2003 show that although investors were concerned about the FDA Warning Letter, they (erroneously) believed that the problems were likely confined to a few rogue salespersons. One user posted, "Its not that hard to sell a great drug guys!!!! [sic] Would someone at GILD please find the dumbass sales reps that keep talking out their ass and have them or the VP in charge of sales and marketing fired before more embarrasement occurs. [sic]" In another message, the poster said: "[A]fter reviewing the specifics, it is clear this is nothing new and a standard reprimand I doubt this will move the stock one penny"
- 251. Another poster wrote, "Relax This is a standard tactic that the FDA starts to utilize when a drug becomes the market leader. This is done primarily to keep the company in line Big pharma gets these letters on a monthly basis " Another poster agreed, writing "I couldn't agree more. FDA always do things like that to cover their ass just, and I mean just, in case if something happens. [sic]"
- 252. Investors apparently believed that the FDA Warning Letter referred to stale transgressions with little implication for ongoing sales. One Yahoo! poster wrote, "Yeah, real timely information. In a letter dated July 29th, about marketing claims in April Whatever, its old news.

[sic]" Another wrote, "This report is as dated and irrelevant to the future growth prospectus of GILD as the EU advisory was relating to Glaxo's study and dated results."

- 253. In short, although investors took notice of the FDA Warning Letter, they did not recognize its significance because they did not understand the scope of the off-label marketing and thus could not understand how the FDA's warning would impact sales.
- 254. On August 14, 2003, Gilead filed its quarterly report on Form 10-Q, for Second Quarter 2003, ended June 30, 2003. The 10-Q was signed by Defendants Martin and Milligan.
- 255. The Second Quarter 2003 10-Q confirmed the previously announced financial results, stating:

Net product sales were \$230.7 million for the three months ended June 30, 2003, compared with \$93.8 million for the quarter ended June 30, 2002, representing an increase of 146%. The increase in product sales is due to the significant increase in the volume of sales of Viread. Sales of Viread in the second quarter of 2003 were \$167.0 million, or 72% of total product sales, compared to \$44.7 million, or 48% of total product sales, in the second quarter of 2002. Of the \$167.0 million, \$115.6 million were U.S. sales and \$51.4 million were international sales. International sales of Viread in the second quarter of 2003 were positively impacted by \$5.0 million due to a more favorable currency environment compared to the second quarter of 2002. We believe U.S. sales in the second quarter were favorably impacted by an increase in wholesaler stocking levels in anticipation of a price increase. We estimate that this higher stocking resulted in \$25.0 to \$30.0 million of additional sales during the second quarter, which may adversely impact sales in the third quarter as wholesalers return to more normal inventory levels and buying patterns. We expect Viread sales to be in the range of \$550 million to \$600 million for the full year 2003.

* * *

In the first six months of 2003, net product sales were \$386.6 million, versus \$164.5 million in the comparable period of 2002, an increase of 135%. Sales of Viread for the six months ended June 30, 2003 were \$274.3 million, or 71% of total product sales, compared to \$71.9 million, or 44% of total product sales, in the six months ended June 30, 2002. *The significant increase in Viread sales is due to increased prescription volume and an increase in U.S. wholesaler inventory levels*. Of the \$274.3 million in Viread sales, \$184.5 million were U.S. sales and \$89.8 million were international sales. International sales of Viread in the first six months of 2003 were positively impacted by \$8.6 million due to the more favorable currency environment compared to the same period last year. We also recognized \$92.2 million in AmBisome sales for the first six months of 2003, a 5% increase over the six months ended June 30, 2002. Reported AmBisome sales in the first six months of 2003 were \$13.2 million higher due to the favorable currency environment. On a volume basis, however, AmBisome sales decreased by 7% in Europe due to increased competition.

(Emphasis added.)

256. The statements in the Second Quarter 2003 10-Q were false and misleading for the same reasons detailed in ¶233 and 242 herein. Defendants' fraudulent promotion of Viread was at the core of increased Viread prescriptions. Increased Viread prescriptions contributed to Gilead's ability to increase the price of Viread in June 2003 which, in turn, increased U.S. drug wholesalers' motivation to overstock their Viread inventory. Defendants' lack of candor regarding the true reasons for Viread's success allowed Defendants to unload millions of dollars worth of Gilead stock.

257. While Defendants' Second Quarter 2003 10-Q briefly addressed the FDA Warning Letter, it did nothing more than disclose its existence; it failed to provide anything close to full and complete disclosure of Defendants' pervasive fraudulent marketing scheme, stating:

Regulatory Process. The products that we develop must be approved for marketing and sale and will be subject to extensive regulation by the FDA and comparable regulatory agencies in other countries. In addition, even after our products are marketed, the products and their manufacturers are subject to continual review. We are continuing clinical trials for AmBisome, Viread, Hepsera and Emtriva for currently approved and additional uses and anticipate filing for marketing approval of additional products over the next several years. If products fail to receive marketing approval on a timely basis, or if approved products are the subject of regulatory changes, actions or recalls, our results of operations may be adversely affected. For example, on August 7th, 2003, the FDA issued a written warning concerning our promotional practices of Viread. The FDA could seek to impose penalties including fines, suspensions of regulatory approvals or promotional activities for a product, product recalls, seizure of products and criminal prosecution if our promotional practices violate federal regulations in the future or we otherwise fail to comply with FDA regulations.

Contrary to Defendants' Second Quarter 2003 Form 10-Q, the FDA Warning Letter was issued on July 29, 2003, not August 7, 2003. See Exhibit F. Rather, the FDA made the Warning Letter public on August 7, 2003. This distinction is important because, as demonstrated by the Individual Defendants' trading records below, Defendants Perry and Bischofberger began unloading their shares of Gilead stock after the Warning Letter was issued, but prior to its public disclosure. Specifically, Defendants Perry and Bischofberger sold more than \$3,000,000 worth of stock each between the date the FDA issued the Warning Letter and the date the FDA made the Warning Letter public. Similarly, Defendant Milligan sold almost \$700,000 worth of stock on August 7, 2003, the very same day the Warning Letter became public. The very next day, on August 8, 2003, Defendant Martin sold more than \$3,000,000 worth of stock.

- 258. Unbeknownst to investors, the disclosure of the FDA Warning Letter had a detrimental effect on Viread sales. Physicians, now alerted to Gilead's illegal marketing efforts and to the safety problems with Viread, were less eager to prescribe it to their patients. Competitors were able to use the FDA Warning Letter as an argument to physicians to choose their own products over Viread.
- 259. Gilead saw a marked drop in prescriptions and sales in the weeks following the disclosure of the letter. Even after prescriptions and sales recovered late in the Third Quarter, they did not go as high as they would have had the letter not issued. Although precise sales figures in the aftermath of the disclosure of the FDA Warning Letter are exclusively in the hands of Defendants, wholesalers, and certain third party organizations that track prescription drug sales (and are not available to Plaintiffs for use at this stage of the litigation), Morgan Stanley's October 29, 2003 report includes a chart of Viread prescriptions on a weekly basis demonstrating a sharp drop in August 2003, and flattened growth for the rest of the third quarter, as compared to previous quarters.
- 260. Viread prescriptions would have fallen even further in the weeks following the disclosure of the FDA Warning Letter, but for the fact that side-effects rendered it dangerous for certain patients to discontinue the drug, as described *supra* at ¶131. Overall, the disclosure of the FDA Warning Letter in the Third Quarter resulted in sales and prescription for the quarter that did not demonstrate the strong growth that investors had come to expect.
- 261. The slow down in growth, coupled with the drop in sales and prescriptions immediately following the FDA Warning Letter disclosure, influenced wholesalers, who monitored sales of Viread very closely in order to gauge how much inventory to keep on hand. Without the strong continued demand that they had come to expect from Viread, wholesalers chose to draw down much more of the excess inventory than they otherwise would have done. As a result, by the end of the quarter, wholesalers reduced their inventories of Viread to as little as *two weeks*' supply, far beneath historical levels for Viread, beneath the industry average of 5.8 weeks, and well beneath what would have been expected had Viread's performance been an accurate reflection of legal demand. In fact, inventory levels were at the lowest level they had been in *four quarters*.

4

9

10

11

12

13

14

15

16

17

18

19

(Emphasis added.)

20 21

2223

24

25

26

2728

262. On October 28, 2003, after the markets closed, Defendants issued a press release reporting Gilead's Third Quarter 2003 financial results and revealing that Viread sales for that quarter would be materially less than expected due to the fact that the level of overstocking by wholesalers was substantially and materially more than previously reported. The press release explained that, as a result, demand for Viread in the third quarter of 2003 was met by sales from existing wholesaler inventory, rather than new sales, stating:

Net revenues from product sales totaled \$194.1 million, up 61 percent from the third quarter of 2002. This growth primarily was driven by higher revenues from Viread® (tenofovir disoproxil fumarate). Sales of Viread were \$115.4 million in the third guarter of 2003, up from \$68.9 million in the third quarter of 2002, an increase of 67 percent. U.S. sales of Viread were \$59.4 million, and sales outside the United States totaled \$56.0 million. Viread sales growth was primarily driven by higher prescription volumes in both the United States and Europe and a favorable European currency environment compared to the same quarter last year. After reviewing NDC prescription trends, IMS inventory data and actual Viread sales, Gilead estimates there was approximately \$33 to \$37 million of inventory reduction by U.S. pharmaceutical wholesalers during the third quarter of 2003 following an equivalent inventory build during the second quarter of 2003. AmBisome® (amphotericin B) liposome for injection sales for the third quarter of 2003 were \$51.6 million, a record high and an increase of 6 percent compared to the third quarter of 2002. Reported AmBisome sales in the third quarter of 2003 were \$6.1 million higher due to the favorable currency environment compared to the same quarter last year. On a volume basis, AmBisome sales decreased by one percent in Europe compared to the third quarter of 2002. Sales of Hepsera® (adefovir dipivoxil 10 mg) totaled \$16.4 million for the third quarter of 2003, up from \$12.4 million in the second quarter of 2003. Since the launch of EmtrivaTM (emtricitabine) in July 2003, sales for the third quarter of 2003 were \$6.0 million.

- 263. The market was stunned by this news. Not only was demand for Viread well below what had been expected, but, contrary to expectations, wholesalers had drawn down the entire amount of the second quarter overstocking rather than purchase additional supplies of Viread. For instance, on October 29, 2003, Bear Stearns issued a research note reporting that Viread wholesale stocking levels were as low as they could possibly get at the two week level. Bear Stearns promptly lowered its fourth quarter projections "[b]ased on estimation of lower end-user demand."
- 264. Morgan Stanley also attributed the disappointing results to "lower end-user demand" and the striking degree to which wholesalers had dumped their Viread supplies rather than refill their inventories: "Wholesalers appear to have managed down their inventory levels for Viread, at least in the short term, from the one-month level previously, to about half of that now. The result of higher

9 10

8

12

13

11

14 15

16 17

18 19

20 21

23 24

22

25 26

28

27

inventories entering the quarter, lower end-user demand entering the quarter, and lower wholesaler target inventories, had a significant effect on the reported 3Q Viread number."

- 265. The disappointing news – lower demand, resulting in wholesalers' decision to reduce their supplies to levels well below what they had been before the overstocking – caused the market to punish Gilead's stock price. Shares of Gilead fell 12%, or \$7.46 per share, from a high of \$59.46 per share on October 28, 2003, to a low of \$50.27 and closing at \$52.00 per share on October 29, 2003. The news also sparked enormous trading volume of 66 million Gilead shares, compared to the average daily volume of 4.6 million – a 1400% increase. The October 28, 2003 press release tacitly admitted that demand for Viread was not as strong as investors were previously led to believe. U.S. drug wholesalers were drawing down very material amounts of Viread inventory and Defendants' fraudulent promotion of Viread, which artificially boosted Viread sales, was continuing to have very detrimental effects on the Company's ability to sustain its sales, financial and operational results.
- 266. A reasonable investor would consider Defendants' misrepresentations in their July 14, 2003 press release, July 14, 2003 Bloomberg News statement, July 31, 2003 press release, August 14, 2003 Form 10-Q, and October 28, 2003 press release as important in their decision making and would have viewed these misrepresented facts as significantly altering the total mix of information made available about Gilead from both a quantitative and qualitative standpoint. Had Plaintiffs, and the other members of the Class, and the marketplace known of Gilead's true financial condition and business prospects, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Gilead securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.
- 267. The market for Gilead's publicly traded securities was open, well-developed, and efficient at all relevant times. As a result of Defendants' materially false and misleading statements, Gilead's publicly traded securities traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired Gilead publicly traded securities relying upon the integrity of the market price of Gilead's publicly traded securities and market information relating to Gilead, and have been damaged thereby, as evidenced by, among

others, the stock price decline on or about October 28, 2003 when artificial inflation was released from Gilead stock.

268. At all relevant times, the material misrepresentations particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false or misleading statements about Gilead's sales, business, product marketing and promotion, prospects, operations and financial results. These material misstatements had the cause and effect of creating in the market an unrealistically positive assessment of Gilead and its sales, products, business, and operations and financial results, thus causing the Company's publicly traded securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's publicly traded securities at artificially inflated prices, thus causing the damages complained of herein, as evidenced by, among others, the stock price decline on or about October 28, 2003 when artificial inflation was released from Gilead stock.

ADDITIONAL SCIENTER ALLEGATIONS

269. As alleged herein, Defendants acted with scienter in that they knew or disregarded with deliberate recklessness that the public documents and statements, issued or disseminated in the name of the Company, were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail throughout this complaint, Defendants, by virtue of their receipt of information reflecting the true facts regarding Gilead, their control over, and/or receipt and/or modification of Gilead's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Gilead, participated in the fraudulent scheme alleged herein.

270. Defendants knew and/or disregarded with deliberate recklessness the falsity and misleading nature of the information that they caused to be disseminated to the investing public. The ongoing fraudulent scheme described in this complaint could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and complicity of the personnel at the highest level of the Company, including each of the Individual Defendants.

- 271. In addition to the foregoing and other facts alleged herein, the following facts provide compelling evidence that Defendants acted with intent to deceive Gilead investors.
- 272. Importantly, the Individual Defendants were motivated to perpetuate the fraudulent scheme and course of conduct described herein so that they could sell their personally-held shares for gross proceeds of over \$20 million at artificially inflated prices.⁷
- 273. Within days after rebutting a Wall Street analyst's concerns regarding inventory overstocking (implying strong demand for Viread) and receiving their second FDA warning letter, Defendants began to unload their Gilead shares throughout the month of August.
- 274. Notwithstanding their access to this and other non-public information, Defendants disposed of the following amounts of their stock:

John C. Martin, President and CEO:

Date	Number of Shares Sold	Price Per Share	Total Value
08/08/2003	2,000	\$63.20	\$126,400
08/08/2003	12,500	\$63.15	\$789,375
08/08/2003	13,000	\$63.00	\$819,000
08/08/2003	22,500	\$62.28	\$1,401,300
TOTAL	50,000 (13.86% of stock and exercised options)		\$3,136,075

⁷ In the Court's Amended Order Granting Defendants' 12(b)(6) Motion to Dismiss the Consolidated Complaint, the Court ruled that Defendants' sales in and of themselves do not show scienter. Figures outlining Defendants' sales are included here because when the Complaint is viewed in its entirety, Defendants' sales further support the strong inference of scienter raised in the Complaint and such sales also provide important context from which to view Defendants' fraudulent scheme.

Mark L. Perry, Executive Vice President, Operations

Date	Number of Shares Sold	Price Per Share	Total Value
08/05/2003	5,000	\$65.39	\$326,950
08/05/2003	5,000	\$65.20	\$326,000
08/05/2003	5,000	\$65.10	\$325,500
08/05/2003	5,000	\$65.05	\$625,250
08/05/2003	8,000	\$65.22	\$521,760
08/05/2003	14,344	\$65.00	\$932,360
08/06/2003	2,500	\$61.17	\$152,925
08/06/2003	2,500	\$62.00	\$155,000
08/06/2003	5,000	\$62.11	\$310,550
TOTAL	52,344 (17.91% on 08/05/2003 and 4.90% on 08/06/2003 of stock and exercised options)		\$3,376,295

John F. Milligan, Senior Vice President and CFO:

Date	Number of Shares Sold	Price Per Share	Total Value
08/07/2003	500	\$63.55	\$31,775
08/07/2003	5,000	\$63.30	\$316,500
08/07/2003	5,500	\$63.21	\$347,655
TOTAL	11,000 (20% of Stock and exercised options		\$695,930

Norbert W. Bischofberger, Executive Vice President, Research & Development:

Date	Number of Shares Sold	Price Per Share	Total Value
08/05/2003	5,000	\$62.56	\$312,800
08/05/2003	10,000	\$63.28	\$632,800
08/05/2003	19,020	\$63.49	\$1,207,579.80

1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
26	
27	

Date	Number of Shares Sold	Price Per Share	Total Value
08/05/2003	21,000	\$63.35	\$1,330,350
08/28/2003	15,000	\$62.68	\$938,250
08/28/2003	20,000	\$62.55	\$1,253,600
TOTAL	90,020 (23.21% on 08/05/2003 and 16.12% on 08/28/2003 of stock and exercised options)		\$5,675,379.80

Anthony Carraciolo, Senior Vice President, Manufacturing:

Date	Number of Shares Sold	Price Per Share	Total Value
08/11/2003	200	\$62.67	\$12,534
08/11/2003	500	\$62.64	\$31,320
08/11/2003	500	\$63.09	\$31,545
08/11/2003	1,100	\$62.68	\$68,948
08/11/2003	1,500	\$63.08	\$94,620
08/11/2003	24,500	\$62.66	\$1,535,170
08/11/2003	26,440	\$62.43	\$1,650,649.20
08/21/2003	100	\$65.73	\$6,573
08/21/2003	100	\$65.61	\$6,561
08/21/2003	400	\$65.71	\$26,284
08/21/2003	600	\$65.59	\$39,354
08/21/2003	700	\$65.62	\$45,934
08/21/2003	2,200	\$65.63	\$144,386
08/21/2003	2,800	\$65.72	\$184,016
08/21/2003	3,300	\$65.64	\$216,612
08/21/2003	3,500	\$65.65	\$229,775
08/21/2003	3,897	\$65.74	\$256,188.78
08/21/2003	4,800	\$65.60	\$314,880

81

FIFTH CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

Number of

Shares Sold

1
2
3
4
5

TOTAL	106,2378		\$6,806,890.98
08/21/2003	11,100	\$65.69	\$729,159
08/21/2003	10,900	\$65.68	\$715,912
08/21/2003	7,100	\$65.70	\$466,470

Price Per

Share

Total Value

William A. Lee, Senior Vice President, Research:

Date

Date	Number of Shares Sold	Price Per Share	Total Value
08/29/2003	15,000	\$66.10	\$991,500
TOTAL	15,000 (19.73% of stock and exercised options)		\$991,500

275. Both the timing of the sales and the sale prices are suspicious. First, all of the Individual Defendants' sales occurred in succession over a twenty-four day period when they were misrepresenting the Company's Viread sales figures and ignoring the impact that would result from the FDA's Warning Letter which sought to curtail Gilead's false and misleading promotion of Viread. This is the first and only time that *all* of the Individual Defendants sold Gilead shares during such a short period of time.

276. Second, contrary to what Gilead disclosed in its Second Quarter 2003 Form 10 Q, the FDA Warning Letter was issued on July 29, 2003, not August 7, 2003. See Exhibit F. Rather, the FDA Warning Letter was made public on August 7, 2003. The public disclosure of the letter shines a bright light on the Individual Defendants' suspicious sales timing. Specifically, Defendants Perry and Bischofberger sold *more than \$3,000,000* worth of stock *each* between the date the FDA issued the FDA Warning Letter and the date it became public. Following suit, Defendant Martin sold more than \$3,000,000 worth of stock on August 8, 2003. Third, and equally troubling, the Individual

⁸ There was insufficient information in Defendant Carraciolo's Form 4 filings with the SEC to allow Lead Plaintiffs to calculate what percentage of stock and exercised options Defendant Carraciolo

Lead Plaintiffs to calculate what percentage of stock and exercised options Defendant Carraciolo sold during the Class Period. However, it is known that Defendant Carraciolo never sold any stock prior to the Class Period.

Defendants sold their shares between \$61.17 to \$66.10 per share, near the stock's peak at \$70.61 and prior to a low of \$50.27 on October 29, 2003.

- 277. Additionally, the Individual Defendants' prior trading history indicates that sales during the Class Period were both unusual and suspicious. In no time prior to the Class Period had all of the Individual Defendants ever sold stock during the same month. In fact, Defendant Carraciolo *never* sold a single share of Gilead stock prior to the Class Period. However, during a twenty-four day period in August 2003 the Individuals Defendants all sold significant amounts of stock near the height of Gilead's artificially inflated share price for proceeds of more than \$20 million.
- 278. The Individual Defendants' knowledge about the false and misleading promotion of Viread, as evidenced by the Untitled FDA Letter and the FDA Warning Letter, as well as their false and misleading statements concerning sales of Viread during Second Quarter 2003, highlight the unusual nature of Defendants' conspicuously well-timed stock sales.
- 279. The unusual circumstances surrounding the Individual Defendants' sales of their stock during a 24-day period in August of 2003 further demonstrate both the Individual Defendants' motive to commit the fraud alleged herein as well as their scienter. As described herein, Defendants acted with scienter in that they knew, or with deliberate recklessness disregarded, that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew, or with deliberate recklessness disregarded, that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Gilead, their control over, and/or receipt and/or modification of Gilead's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Gilead, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE MARKET DOCTRINE

2

1

3

6

9

11

13

17

21

22

4 5

7 8

10

12

14 15

16

18

19 20

23 24

25 26 27

28

- 280. At all relevant times, the market for Gilead's publicly traded securities was an efficient market for the following reasons, among others:
- (a) Gilead's securities met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;
- (b) as a regulated issuer, Gilead filed periodic public reports with the SEC. including reports on Form S-3;
- (c) Gilead regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
- (d) Gilead was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.
- 281. As a result, the market for Gilead's publicly traded securities promptly digested current information regarding Gilead from all publicly-available sources and reflected such information in Gilead's securities prices. Under these circumstances, all purchasers of Gilead's publicly traded securities during the Class Period suffered similar injury through their purchase of Gilead's publicly traded securities at artificially inflated prices and a presumption of reliance applies.

NO SAFE HARBOR

282. The federal statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the

1 ex 2 Do 3 fo 4 lo 5 by 6 to 7 ce 8 Do 9 ha

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Gilead who knew that those statements were false when made. Moreover, to the extent that Defendants issued any disclosures designed to "warn" or "caution" investors of certain "risks," those disclosures were also false and misleading since they did not disclose that Defendants were actually engaging in the very actions about which they purportedly warned and/or had actual knowledge of material adverse facts undermining such disclosures.

COUNT I

FOR VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10b-5 PROMULGATED THEREUNDER AGAINST ALL DEFENDANTS

- 283. Plaintiffs repeat and reallege the allegations set forth above as though fully set forth herein. This claim is asserted against all Defendants.
- During the Class Period, Gilead and the Individual Defendants, and each of them, carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Gilead's publicly traded securities; and (iii) cause Plaintiffs and other members of the Class to purchase Gilead's publicly traded securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Gilead and the Individual Defendants, and each of them, took the actions set forth herein.
- 285. These Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Gilead's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. These Defendants are sued as primary participants in the wrongful

28

and illegal conduct charged herein. The Individual Defendants are also sued as controlling persons of Gilead, as alleged below.

286. In addition to the duties of full disclosure imposed on Defendants as a result of their making of affirmative statements and reports, or participating in the making of affirmative statements and reports to the investing public, they each had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-X (17 C.F.R. § 210.01 et seq.) and S-K (17 C.F.R. §229.10 et seq.) and other SEC regulations, including accurate and truthful information with respect to the Company's operations, sales, product marketing and promotion, financial condition and operational performance so that the market prices of the Company's publicly traded securities would be based on truthful, complete and accurate information.

- 287. Gilead and each of the Individual Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, business practices, sales performance, product marketing and promotion, operations and future prospects of Gilead as specified herein.
- 288. These Defendants each employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Gilead's value and performance and continued substantial sales, financial and operational growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Gilead and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Gilead's securities during the Class Period.
- 289. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: a) each of the Individual Defendants was a high-level executive and/or director at the Company during the Class Period; b) each of the Individual Defendants, by

virtue of his responsibilities and activities as a senior executive officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal sales and marketing plans, projections and/or reports; c) each of the Individual Defendants enjoyed significant personal contact and familiarity with each other and were advised of and had access to other members of the Company's management team, internal reports, and other data and information about the Company's financial condition and performance at all relevant times; and d) each of the Individual Defendants was aware of the Company's dissemination of information to the investing public which each knew or recklessly disregarded was materially false and misleading.

290. Each of these Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with deliberately reckless disregard for the truth in that each failed to ascertain and to disclose such facts, even though such facts were available to each of them. Such Defendants' material misrepresentations and/or omissions were done knowingly or with deliberate recklessness and for the purpose and effect of concealing Gilead's operating condition, sales, product marketing and promotional practices and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and misstatements of the Company's financial condition and performance throughout the Class Period, each of the Individual Defendants, if he did not have actual knowledge of the misrepresentations and omissions alleged, was reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

291. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market prices of Gilead's securities were artificially inflated during the Class Period. In ignorance of the fact that market prices of Gilead's publicly traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or disregarded with deliberate recklessness by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Gilead

securities during the Class Period at artificially high prices and were damaged thereby, as evidenced by, among others, the stock price decline on or about October 28, 2003 when artificial inflation was released from Gilead stock.

- 292. At the time of said misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known of the true performance, sales, marketing, promotion and other fraudulent business practices, future prospects and intrinsic value of Gilead, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Gilead publicly traded securities during the Class Period, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.
- 293. By virtue of the foregoing, Gilead and the Individual Defendants have each violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.
- 294. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period, as evidenced by, among others, the stock price decline on or about October 28, 2003 when artificial inflation was released from Gilead stock.

COUNT II

FOR VIOLATIONS OF SECTION 20(A) OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANTS

- 295. Plaintiffs repeat and reiterate the allegations as set forth above as if set forth fully herein. This claim is asserted against the Individual Defendants.
- 296. Each of the Individual Defendants acted as a controlling person of Gilead within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions with the Company, participation in and/or awareness of the Company's operations and/or intimate knowledge of the Company's fraudulent marketing and promotions and actual performance, each of the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and

dissemination of the various statements which Plaintiffs contend are false and misleading. Each of the Individual Defendants was provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

- 297. In addition, each of the Individual Defendants had direct involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.
- 298. As set forth above, Gilead and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their controlling positions, each of the Individual Defendants is liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period, as evidenced by, among others, the stock price decline on or about October 28, 2003 when artificial inflation was released from Gilead stock.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on their own behalf and on behalf of the Class, pray for relief and judgment, as follows:

- A. Declaring that this action is a proper class action, and certifying Plaintiffs as class representatives pursuant to Rule 23 of the Federal Rules of Civil Procedure and Plaintiffs' counsel as Lead Counsel for proposed Class;
- B. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
 - D. Such other and further relief as the Court deems appropriate.

1	JURY TRIA	L DEMANDED
2	Plaintiffs hereby demand a trial by jury	·.
3	DATED: July 10, 2009	KAPLAN FOX & KILSHEIMER LLP
4		
5		
6		/s/ LAURENCE D. KING LAURENCE D. KING
7		350 Sansome Street, Suite 400
8		San Francisco, CA 94104 Telephone: 415-772-4700
9		Fax: 415-772-4707 email: lking@kaplanfox.com
10		Liaison Counsel for Plaintiffs
11		Joshua H. Vinik (<i>admitted pro hac vice</i>) jvinik@milberg.com
12		Lori G. Feldman (admitted pro hac vice) lfeldman@milberg.com
13		Ross Brooks (admitted pro hac vice) rbrooks@milberg.com
14		MILBERG LLP One Pennsylvania Plaza
15		New York, NY 10119-0165 Telephone: 212-594-5300
16		Fax: 212-868-1229
17		David J. George (admitted pro hac vice) dgeorge@csgrr.com
18		Robert J. Robbins (admitted pro hac vice) rrobbins@csgrr.com
19		Holly Kimmel (admitted pro hac vice) hkimmel@csgrr.com
20		COUGHLIN STOIA GELLER RUDMAN & ROBBINS LLP
21		120 E. Palmetto Park Road, Suite 500 Boca Raton, FL 33432
22		Telephone: 561-750-3000 Fax: 561-750-3364
23		Co-Lead Counsel for Plaintiffs
24		, and the second
25		
26		
27		
28		
	H	00

PROOF OF SERVICE

2

3

4

5 6

7

8

9

10

11

12

13 14

15

16 17

18

19

20

21

22 23

24 25

26

27 28

I, Adrianna D. Gutierrez, declare that I am over the age of eighteen (18) and not a party to the within action. I am employed in the law firm of Kaplan Fox & Kilsheimer LLP, 350 Sansome Street, Suite 400, San Francisco, California 94111.

On July 10, 2009, I used the Northern District of California's Electronic Case Filing System, with the ECF registered to Laurence D. King to file the following document(s):

FIFTH CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF FEDERAL **SECURITIES LAWS**

The ECF system is designed to send an e-mail message to all parties in the case, which constitutes service. The parties served by e-mail in this case are found on the Court's Electronic Mail Notice List.

On this date, I served the below parties:

Jack G. Fruchter ABRAHAM FRUCHTER & TWERSKY LLP One Penn Plaza, Suite 2805 New York, NY 10119	Robert A. Jigarjian JIGARJIAN LAW OFFICE 128 Tunstead Avenue San Anselmo, CA 94960
James M. Orman LAW OFFICES OF JAMES M. ORMAN 1845 Walnut Street, 14th Floor Philadelphia, PA 19103 jorman@sdbslaw.com	Lauren Block Jennifer J. Sosa MILBERG LLP One Pennsylvania Plaza, 49 th Floor New York, NY 10119-0165 Telephone: 212-594-5300 Fax: 212-868-1229
Holly W. Kimmel Coughlin Stoia Geller Rudman & Robbins LLP 120 E. Palmetto Park Road Suite 500 Boca Raton, FL 33432-4809	

(BY FACSIMILE) I sent such document from facsimile machine on the above date. I certify that said transmission was completed and that all pages were received and that a report was generated by the facsimile machine which confirms said transmission and receipt.

(U.S. MAIL) I placed the sealed envelope(s) for collection and mailing by following ordinary business practices of Kaplan Fox Kilsheimer LLP. I am readily familiar with Kaplan Fox Kilsheimer LLP's practice for collecting and processing of correspondence for mailing with the United States Postal Service, said practice being that, in the ordinary course of business,

correspondence with postage fully prepaid is deposited with the United States Postal Service the 1 same day as it is placed for collection. 2 (PERSONAL SERVICE) I caused personal delivery of the document(s) listed above the 3 person(s) at the address(es) set forth below. 4 XXX (BY OVERNIGHT DELIVERY) I placed the sealed envelope(s) or package(s) designated 5 by the express service carrier for collection and overnight delivery by following the ordinary business practices of Kaplan Fox Kilsheimer LLP. I am readily familiar with Kaplan Fox Kilsheimer LLP's practice for collecting and processing of correspondence for overnight delivery, said practice being that, in the ordinary course of business, correspondence for overnight delivery is deposited with delivery fees paid or provided for at the carrier's express service offices for next-day delivery the same day as the correspondence is placed for collection. 8 I declare under penalty of perjury under the laws of the United States of America and the 9 10 State of California that the foregoing is true and correct. Executed July 10, 2009, at San Francisco, California. 11 12 Adrianna D. Gotierrez 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28

FIFTH CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

Case No.: C-03-4999-SI

Case3:03-cv-04999-SI Document234-2 Filed07/10/09 Page33 of 33